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## **DETAILED ACTION**

### ***Examiner's Amendment***

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Stephan Scribner on 17 March 2008.

The application has been amended as follows:

In Claim 24: On line 6, after "said at least one substrate thereinto" insert --, the partitioning element not including an indicator agent that interacts with said biological molecule or said at least one substrate --.

Support for this amendment can be found in Examples 1 and 19 of Applicant's specification. Applicant describes a polymer partitioning element preparation procedure that does not require the addition of an indicator agent to the partitioning element.

### ***Allowable Subject Matter***

Claims 24-35 and 54-57 are allowed.

With respect to independent claim 24, the prior art does not disclose in the claimed environment a solid partitioning element that allows partitioning of only one of a biological molecule and a substrate, such that the partitioning element does not include an indicator agent

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that interacts with the biological molecule or the substrate. The Lubbers (US 4272484) and Hsu (US 4712865) references represent the closest prior art in that each describes the use of a polymer membrane capable of promoting the selective partitioning of a desired biological product. Lubbers in particular describes a glucose detection system that involves the formation of a biological product (oxygen) upon the reaction between an enzyme and a substrate. The product is allowed to move through the membrane of an optical probe upon its formation. Lubbers and Hsu, however, each describe that indicator agents must be present on and within the partitioning element in order to achieve detection. Lubbers and Hsu teach away from the use of a partitioning element absent an indicator agent.

The Collins reference also represents pertinent prior art. Collins discloses a system for detecting the presence of an organism in which a substrate and an enzyme react to form a biological molecule. Collins, however, teaches that partitioning of the biological molecule or the substrate is accomplished using solvent extraction as opposed to a solid partitioning means.

The Wolfbeis, Loeb and Vadgama references are also relevant prior art in that each patent discloses a partitioning means capable of isolating an enzyme from contaminants and debris within a solution. However, Wolfbeis and Loeb each teach that the enzyme-substrate reaction takes place within reaction area formed within the partitioning membrane. As a result, there is no partitioning of an individual reaction component because the enzyme, substrate, and biological reaction product are all present within the reaction area. Vadgama is also deficient because Vadgama teaches detection of a species after having passed through the membrane, but does not teach detection of the species in the membrane. Vadgama does not teach a partitioning element mass into which a compound partitions.

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*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner, Art Unit 1797

/Nathan A Bowers/  
Examiner, Art Unit 1797